REMARKS

Claims 1-19 are pending and are rejected.

Claims 12, 17 and 19 are canceled.

Applicant has amended the phrase "an agent consisting essentially of" to "a composition consisting essentially of," as suggested by the Examiner in the telephonic interview.

Applicant respectfully requests reconsideration of the Examiner's rejections for the following reasons.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 1-19 are rejected under 35 U.S.C. § 112 ¶ 2 as indefinite. Applicant respectfully disagrees.

Applicant has used the open-ended transitional phrase "comprising" with reference to the method (claim 1 is a method claim). Applicant has used the partially-closed transitional phrase "consisting essentially of" with reference to the agent. Thus, the agent does not include active ingredients other than hGH; the method can include steps other than determining a response, selecting a dose and administering the dose.

As applicant has stated in the previous Amendment, the phrase "an agent consisting essentially of" does not include other hormones or other bioactive compounds (Amendment at page 4; instant specification at least at page 3, lines 19-21, and page 5, lines 16-19). As the court held in *In re Janakirama-Rao*, 137 U.S.P.Q. 893, 896 (C.C.P.A. 1963), "[t]he word 'essentially' opens the claims to the inclusion of ingredients which would

not materially affect the basic and novel characteristics of appellant's compositions as defined in the balance of the claim, according to the applicable law." *See also* MPEP 2111.03 ("The transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention.").

Regarding the phrases "said maintenance dose is administered monthly" and "said dose producing said optimal response is administered monthly," Applicant has amended claims 2, 11 and 15 to provide that the daily dose is recalculated to a monthly dose based on the individualized bioavailability data, as pointed out by the Examiner.

Regarding the term "about," applicant respectfully maintains that it is not indefinite. Applicant has stated that the typical initial dosage is 2 µg/kg/day for a male and 4 µg/kg/day for a female, and that the typical maintenance dosage is in the range of 10-14 µg/kg/day for a male and 14-20 µg/kg/day for a female. "The meaning of the word 'about' is dependent on the facts of a case, the nature of the invention, and the knowledge imparted by the totality of the earlier disclosure to those skilled in the art." *Eiselstein v. Frank*, 34 U.S.P.Q.2d 1467, 1471 (Fed. Cir. 1995); *see also Pall Corp. v. Micron Separations, Inc.*, 36 U.S.P.Q.2d 1225, 1229 (Fed. Cir. 1995) ("[T]he word 'about' does not have a universal meaning in patent claims, and . . . the meaning depends on the technological facts of the particular case.").

Eiselstein disclosed an alloy, with nickel being from *about* 45% to *about* 55% of the alloy. The court held the term "about" not indefinite under 35 U.S.C. § 112 ¶ 2. The applicant "need not be bound to maximum precision for the nickel content when the whole

tenor of his disclosure indicates approximation." *Id.* (emphasis added). Applicant discloses a method of replenishing human growth hormone in adults in an individualized manner within the claimed range.

Applicant thus believes the amended claims and above explanations fully overcome the rejections under 35 U.S.C. § 112.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

Claims 1, 4-10, 12-14, 18, and 19 are rejected under 35 U.S.C. § 102(b) as anticipated by Chein. Applicant respectfully disagrees.

Applicant teaches replenishing only hGH in an individualized manner. Chein, on the other hand, teaches replenishing hGH as well as at least two other hormones that are below physiological levels.

Again, applicant respectfully asserts that the use of "an agent consisting essentially of hGH" does not anticipate Chein. As discussed above, "recital of 'essentially' along with 'consisting of' is regarded as rendering the claim open only for the inclusion of unspecified ingredients which do not materially affect the basic and novel characteristics of the composition." *In re Janakirama-Rao*, 137 U.S.P.Q. at 894. Therefore, applicant's disclosure does not include other hormones or bioactive compounds, as they would materially affect the basic and novel characteristics of the agent.

The Examiner has suggested the use of "an agent consisting of hGH" instead of "an agent consisting essentially of hGH." However, Applicant has used the partially-closed transitional phrase "consisting essentially of" to allow the addition of ingredients that

do not materially affect the basic and novel characteristics of the invention. Use of the term "consisting of" limits Applicant to only hGH.

The Examiner also asserts that Chein teaches the administration of hGH to males at 7.1 µg/kg/day, which is "about" 10-14 µg/kg/day, and to females at 10.4 µg/kg/day, which is "about" 14-20 µg/kg/day. Although the use of "about" avoids a strict numerical boundary to the specified parameter, it does not broaden the parameter to encompass the disclosure in Chein. "In general, a term such as 'about' is not subject to a precise construction but is dependent on the factual situation presented." *Jeneric/Pentron, Inc. v. Dillon Co., Inc.*, 54 U.S.P.Q.2d 1086 (Fed. Cir. 2000). In *Eiselstein*, previously described, the Federal Circuit held that "[w]hatever the term 'about' means in this context, it is clear that it does not extend 55% to encompass 60%. Moreover, the 10% range of 45-55%, even if it is an approximate 'about' 45-55%, is not the same as a very different 10% range, viz., 50-60%." *Eiselstein*, 34 U.S.P.Q.2d at 1471.

The Examiner additionally maintains that Chein is an individualized process. Applicant respectfully disagrees. Chein adjusts the dose of hGH until target levels of IGF-1 are achieved (column 11, line 59). Applicant's disclosure does not require increasing doses of hGH until a target level of IGF-1 is reached. Instead, only if the individual does not have a response and IGF-1 levels are not optimal will a serially increasing dose be given. Additionally, Chein does not disclose serially increasing doses until target levels of IGF-1 are reached. The dosages of hormone supplementation are simply adjusted until the target levels of IGF-1 are reached (Chein, column 11, lines 54-59). No direction is given regarding the adjusted amounts.

CONCLUSION

Applicant has submitted all fees believed to be necessary herewith. Should any additional fees or surcharges be deemed necessary, the Examiner has authorization to charge fees or credit any overpayment to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney if there are any questions or issues.

Respectfully submitted,

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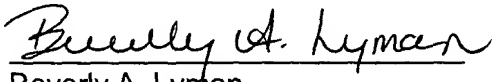

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Cancel claims 12, 17 and 19.

Amend the claims as follows:

1. (AMENDED) A method of replenishing human growth hormone (hGH) in an adult human comprising administering a[n agent] composition consisting essentially of recombinant hGH in an individualized dose to replenish hGH, said individualized dose determined by

(1) determining a response of said human to an initial dose of said [agent] composition administered on a daily basis,

(2) thereafter determining a response of said human to serially increased doses of said [agent] composition administered on a daily basis,

(3) selecting said dose of [agent] composition from (2) producing an optimal replenishment to administer as a maintenance dose, and

(4) thereafter administering said dose from (3) to replenish hGH.

2. (AMENDED) The method of claim 1 wherein said maintenance dose is calculated from a daily dose to a monthly dose based on individualized bioavailability data and is administered monthly.

10. (AMENDED) A method of providing an adult human with human growth hormone (hGH) comprising

administering a[n agent] composition consisting essentially of recombinant hGH to said human on a daily basis at an initial dose to produce an initial response to said [agent] composition,

thereafter administering at least one serially increased initial dose of said [agent] composition on a daily basis and evaluating said human's response to said serially increased dose to produce an individualized optimal response to said [agent] composition, and

thereafter administering said dose producing said optimal response as a maintenance dose.

11. (TWICE AMENDED) The method of claim 10 wherein said dose producing said optimal response is calculated from a daily dose to a monthly dose based on individualized bioavailability data and is administered monthly.

15. (AMENDED) The method of claim 14 wherein said maintenance dose is calculated from a daily dose to a monthly dose based on individualized bioavailability data and is administered monthly.